POLICY: Neurology – Qalsody Utilization Management Medical Policy

- Qalsody™ (tofersen intrathecal injection – Biogen)

EFFECTIVE DATE: 10/16/2023
LAST REVISION DATE: 12/10/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Qalsody, an antisense oligonucleotide, is indicated for the treatment of **amyotrophic lateral sclerosis (ALS)** in adults who have a **mutation** in the **superoxide dismutase 1 (SOD1) gene**.[1]

Guidelines

The American Academy of Neurology (AAN) practice parameter on the care of patients with ALS (last updated 2009; reaffirmed 2023) does not address Qalsody, Relyvrio, Radicava ORS, or Radicava IV.[2,3] The practice parameter states that riluzole is safe and effective for slowing disease progression to a modest degree and should be offered to patients with ALS. However, riluzole may result in fatigue in some patients and if the risk of fatigue outweighs modest survival benefits, discontinuation of riluzole may be considered. Referral to a specialized multidisciplinary clinic should be considered for patients with ALS to optimize health care delivery, prolong survival, and enhance quality of life.

The European Federation of Neurological Societies (EFNS) guidelines on the clinical management of ALS (2012) also recommend patients be offered treatment with riluzole as early as possible after diagnosis.[4] Qalsody is not mentioned in these guidelines. The Canadian best practice recommendations for the management of ALS state that riluzole has demonstrated efficacy in improving survival in ALS and there is evidence that riluzole prolongs survival by a median duration of 3 months.[5] Riluzole should be started soon after the diagnosis of ALS. In a select group of patients, Radicava has been shown to slow decline on the ALS Functional Rating Scale-Revised (ALSFRS-R) scores compared against intravenous (IV) placebo over a 6-month period. The following patients have demonstrated a benefit of Radicava: patients with a disease duration < 2 years, forced vital capacity > 80%, all ALSFRS-R subcomponent scores > 2, and patients who have demonstrated steady decline in the ALSFRS-R over a 3-month period. Evidence for benefit of Radicava IV at other stages of ALS have not been demonstrated. Risks and benefits as well as individualized goals should be considered and discussed before starting therapy with Radicava IV. Qalsody is not mentioned in these guidelines.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Qalsody. Approval is recommended for those who meet the Criteria and Dosing for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1

month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Qalsody as well as the monitoring required for adverse events and long-term efficacy, approval requires Qalsody to be prescribed by, or in consultation with a neurologist with expertise in the diagnosis of ALS.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Qalsody is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Amyotrophic Lateral Sclerosis (ALS)**. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets EACH of the following (i through vii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has a diagnosis of ALS with both of the following (a and b):
       - **a)** Muscle weakness attributed to ALS; AND
       - **b)** Documentation of SOD1 mutation; AND
     - **iii.** The patient has a baseline measure of the plasma neurofilament light chain (NfL); AND
     - **iv.** The patient is not dependent on invasive ventilation or tracheostomy; AND
     - **v.** The patient has a predicted slowed vital capacity (SVC) ≥ 50%; AND
     - **vi.** Provider attestation that the patient's baseline functional ability has been documented prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.); AND
     - **vii.** The medication is prescribed by a neurologist.
   - **B)** Patient is Currently Receiving Qalsody. Approve for 6 months if the patient meets EACH of the following (i through v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Provider attestation the patient has slowed disease progression from baseline; AND
     - **iii.** Provider attests there has been an improvement in the plasma neurofilament light chain (NfL) levels compared to baseline; AND
     - **iv.** The patient is not dependent on invasive ventilation or tracheostomy; AND
     - **v.** The medication is prescribed by a neurologist.

   Dosing. The dose of Qalsody does not exceed 100mg (1 vial) on days 1, 15 and 29, followed by a maintenance dose of 100mg (1 vial) every 28 days.

CONDITIONS NOT RECOMMENDED FOR APPROVAL
Coverage of Qalsody is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Qalsody™ intrathecal injection [prescribing information]. Cambridge, MA: Biogen; April 2023.
2. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). *Neurology*. 2009 (reaffirmed 2023);73(15):1227-1233.
3. Miller RG, Jackson CE, Kasarskis EJ, et al. Practice parameter update: the care of the patient with amyotrophic lateral sclerosis: drug, nutritional, and respiratory therapies (an evidence-based review). *Neurology*. 2009;73:1218-1226.
4. Andersen PM, Abrahams S, Borasio GD, et al. EFNS guidelines on the clinical management of amyotrophic lateral sclerosis (MALS) – revised report of an EFNS task force. *Eur J Neurol*. 2012;19(3):360-375.
5. Shoesmith C, Abrahao A, Benstead T, et al. Canadian best practice recommendations for the management of amyotrophic lateral sclerosis. *CMAJ*. 2020;192(46):E1453-E1468.
6. Miller TM, Cudkowicz ME, Genge A, et al. Trial of antisense oligonucleotide tofersen for *SOD1* ALS. *N Engl J Med*. 2022;387:1099-110.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/24/2023
UCare Update	Created Medicaid specific policy as Qalsody now participates in the Medicaid Drug Rebate Program	9/14/2023
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Update	Updated policy to target all UCare plans. Prior to this the only target was Medicaid. Added requirement of baseline measurement of plasma neurofilament light chain (NfL) levels and attestation of improvement for continuation.	12/10/2024